Filed 11/10/20 (unmodified opinion attached)

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

(Sacramento)

AMERICAN CHEMISTRY COUNCIL, Plaintiff and Appellant, v. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT et al., Defendants and Respondents; NATURAL RESOURCES DEFENSE COUNCIL, Real Party in Interest and Respondent.	C079078 (Super. Ct. No. 34201300140720CUWMGDS) MODIFICATION OF OPINION [NO CHANGE IN JUDGMENT]

THE COURT:

It is ordered that the opinion filed herein on October 19, 2020, be modified as follows:

1. On page 1, in the editorial information of the opinion replace "National" with "Natural" in the name of the Real Party in Interest and Respondent to read "Joshua R.

Purtle, Jennifer A. Sorenson, Michael E. Wall, Avinash Kar for Real Party in Interest Natural Resources Defense Council."

2. On page 3, in the second paragraph, first line, replace the word "National" with "Natural" so the sentence reads in part: "On the same day as the DART-IC determination, real-party-in-interest Natural Resources Defense Council (NRDC) petitioned OEHHA."

3. On page 6, footnote 5, within the last sentence that reads, "BPA had been identified by NTP as a reproductive intoxicant," replace "intoxicant" with "toxicant" so the sentence now reads in part: "BPA had been identified by NTP as a reproductive toxicant."

4. On page 20, in the third full paragraph that reads, "OEHHA emphasized the deferential standard of review to be accorded to it in a case such as this, involving highly technical record," insert the word "a" between the word "involving" and "highly" so the sentence now reads: "OEHHA emphasized the deferential standard of review to be accorded to it in a case such as this, involving a highly technical record addressing scientific material."

5. On page 23, in the second sentence of the first full paragraph that reads, "In response to the question ' "Can [BPA] affect human development or reproduction?" ' The report answered, 'possibly,' " replace the capital "T" in the word "The" before the word "report" with a lower case "t" so that it now reads: "In response to the question ' "Can [BPA] affect human development or reproduction?" ' the report answered, 'possibly.' "

On page 52, in the last sentence in the first paragraph that reads, "Therefore, we turn to the record to consider whether OEHHA's determination that NTP considered criteria in subdivision (g) and whether biological plausibility can be determined from the

monograph and the studies upon which it relied," delete the word "whether" between consider and OEHHA's determination.

This modification does not change the judgment.

BY THE COURT

……/s/
BLEASE, Acting P. J.

……./s/
MURRAY, J.

……./s/
DUARTE, J.

Filed 10/19/20 (unmodified opinion)

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

(Sacramento)

AMERICAN CHEMISTRY COUNCIL, Plaintiff and Appellant, v. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT et al., Defendants and Respondents; NATURAL RESOURCES DEFENSE COUNCIL, Real Party in Interest and Respondent.	C079078 (Super. Ct. No. 34201300140720CUWMGDS)

APPEAL from a judgment of the Superior Court of Sacramento County, Timothy M. Frawley, Judge. Affirmed.

Gibson, Dunn & Crutcher, Daniel M. Kolkey, Theodore J. Boutrous, Patrick W. Dennis, Kahn A. Scolnick, Daniel S. Nowicki, Vanessa C. Adriance for Plaintiff and Appellant American Chemistry Council.

Joshua R. Purtle, Jennifer A. Sorenson, Michael E. Wall, Avinash Kar for Real Party in Interest National Resources Defense Council.

Arnold & Porter and Trenton H. Norris as Amicus Curiae Grocery Manufacturers Association for Plaintiff and Appellant American Chemistry Council.

Kamala D. Harris and Xavier Becerra, Attorneys General, Susan S. Fiering, Supervising Deputy Attorney General, Harrison M. Pollak, Deputy Attorney General for Defendants and Respondents Office of Environmental Health Hazard Assessment, et al.

At issue in this case is whether the decision by the Office of Environmental Health Hazard Assessment (OEHHA) to list Bisphenol A (BPA) as a chemical known to cause reproductive toxicity under Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), was an abuse of discretion. OEHHA is our state's lead agency for Proposition 65. BPA is used primarily to coat food and beverage packaging and containers.

Proposition 65 was enacted by the voters to protect the people of California and its water supply from harmful chemicals. Proposition 65 requires the Governor to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. Health and Safety Code section 25249.8,[1] added by Proposition 65, provides the listing obligations and sets forth four independent "listing mechanisms" by which a chemical can be listed under Proposition 65, including the "state's qualified expert" listing mechanism and the "authoritative body" listing mechanism. (§ 25249.8, subds. (a) & (b).)[2]

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[1] Further undesignated statutory references are to the Health and Safety Code in effect at the time of the proceedings.

[2] In pertinent part, section 25249.8 provides: "(a) On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d). [¶] (b) A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion

The National Toxicology Program - Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR), established by the National Toxicology Program (NTP), published a "Monograph on the Potential Human Reproductive and Developmental Effects of [BPA]" (the monograph) in 2008.[3] Thereafter, the Developmental and Reproductive Toxicant Identification Committee (DART-IC), considered whether to list BPA as a reproductive toxicant under the "state's qualified experts" listing mechanism of section 25249.8, subdivision (b). DART-IC is a committee of OEHHA and is our state's panel of qualified scientific experts appointed by the Governor. After considering the monograph, DART-IC voted not to list BPA as a reproductive toxicant.

On the same day as the DART-IC determination, real-party-in-interest National Resources Defense Council (NRDC) petitioned OEHHA, requesting that OEHHA list BPA under Proposition 65 on the theory that it had been identified as a reproductive toxicant by an authoritative body, specifically NTP-CERHR, and therefore it was subject to listing under the separate authoritative body listing mechanism of section 25249.8, subdivision (b). OEHHA is authorized by statute and regulation to determine whether an authoritative body has identified a chemical as a reproductive toxicant. After reviewing the monograph, OEHHA issued a notice of intent to list BPA as a chemical known to the state to cause reproductive toxicity and ultimately determined that it should be listed pursuant to the authoritative body listing mechanism, despite the state's qualified experts, DART-IC, having decided against listing BPA.

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of the *state's qualified experts* it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or *if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity,* or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity." (Italics added.)

[3] "NTP" and "NTP-CERHR" are occasionally used interchangeably, both by the parties and herein.

The American Chemistry Council (ACC) commenced this action seeking to enjoin OEHHA from listing BPA. In an amended complaint, ACC sought a peremptory writ of mandate directing OEHHA not to list BPA. The trial court denied the requested relief.

ACC appeals, asserting that OEHHA abused its discretion in: (1) refusing to consider the DART-IC determination against listing BPA; (2) concluding that NTP formally identified BPA as a reproductive toxicant in the monograph;[4] and (3)

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[4] As ACC points out, OEHHA's website states that, for purposes of Proposition 65, "reproductive toxicity" includes three endpoints: male reproductive toxicity, female reproductive toxicity, and *developmental toxicity*. (OEHHA (Nov. 1, 1993, Criteria for Recommending Chemicals for Listing as "Known to the State to Cause Reproductive Toxicity," at <https://oehha.ca.gov/media/downloads/proposition-65/proposition-65/dartcriterianov1993.pdf> [as of October 2, 2020], archived at: <https://perma.cc/9KSK-2TMJ> (Criteria for Recommending Listing), italics added.) Through proceedings unrelated to these, as of May 11, 2015, BPA has been listed by the DART-IC under the state's qualified expert listing mechanism of Proposition 65 as a chemical known to the state to cause *female reproductive toxicity*. (Regs. § 27001, subd. (c).) ACC points out that the DART-IC panel that made this listing determination consisted of people who had been substituted for those who appeared on the panel that made the determination at issue in this case, and the later determination was not made based on the monograph at issue here. OEHHA responds that all DART-IC appointments are made by the Governor (Cal. Code Regs., tit. 27, § 25302, subd. (b)(3)), who made the appointments in 2012, several years after the first DART-IC meeting on BPA in 2009. In any event, at issue in these proceedings is whether OEHHA's decision to list BPA as a chemical known to the state to cause *developmental toxicity* was an abuse of discretion. Developmental toxicity is defined as "adverse effects on the products of conception," including "[e]mbryo/fetal mortality . . . malformations, structural abnormalities and variations, altered fetal growth, and change in gestational age at delivery," postnatal parameters "including growth and development, physiological deficits and delay, neurological, neurobehavioral and psychological deficits, altered sex ratio, abnormal sexual development or function, and morbidity or mortality," "[t]ransplacental carcinogenesis," and "[s]omatic or genetic. . . mutations in the conceptus." (Criteria for Recommending Chemicals for Listing, at <https://oehha.ca.gov/media/downloads/proposition-65/proposition-65/dartcriterianov1993.pdf> [as of October 2, 2020], archived at: <https://perma.cc/9KSK-2TMJ>.) Here, the terms reproductive toxicity and developmental toxicity are used interchangeably throughout the record and briefing and as a necessary consequence, so do we. (See *Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, 1271, fn. 7

determining that NTP concluded that studies in experimental animals indicated that there was sufficient data to establish that an association between adverse reproductive effects in humans and BPA is "biologically plausible" within the meaning of that term as it is used in OEHHA's own regulation. As we shall discuss, OEHHA's position as to biological plausibility is based on, among other things, the following presumption: chemicals that cause harm in experimental animals will also cause similar harm in humans in the absence of evidence to the contrary.

We affirm.

FACTUAL AND PROCEDURAL BACKGROUND

BPA

BPA is a chemical used primarily in the production of polycarbonate plastics and epoxy resins. Polycarbonate plastics are used in food and drink packaging and containers. Epoxy resins are used as lacquers to coat metal products including food cans, bottle tops, and water pipes. BPA has other, less common, uses as well. Human exposure to BPA occurs primarily through diet. BPA "can migrate into food from food and beverage containers with internal epoxy resin coatings and from consumer products made of polycarbonate plastic such as baby bottles, tableware, food containers, and water bottles."

The Monograph

The NTP established the NTP-CERHR in June 1998 "to provide timely, unbiased, scientifically sound evaluations of the potential for adverse effects on reproduction or development resulting from human exposures to substances in the environment." The NTP-CERHR expert panel on BPA completed an evaluation of BPA in August 2007. NTP-CERHR published its monograph in September 2008.

(*Exxon Mobil*) [Proposition 65 use of the term "reproductive toxicity" includes "developmental toxicity"].)

The monograph stated that it is possible that BPA can affect human development or reproduction. The monograph, which primarily addressed studies in laboratory animals, stated: "Although there is no *direct evidence* that exposure of people to [BPA] adversely affects reproduction or development, studies with laboratory rodents show that exposure to high dose levels of [BPA] during pregnancy and/or lactation can reduce survival, birth weight, and growth of offspring early in life, and delay the onset of puberty in males and females." (Italics added.) The monograph characterized these " 'high' dose effects" in the animal studies as "not scientifically controversial," and stated that they provided "*clear evidence* of adverse effects on development in laboratory animals."[5] (Italics added.) The monograph further stated that the "NTP finds that there is *clear evidence* of adverse developmental effects at 'high' doses of [BPA] in the form of fetal death, decreased litter size, or decreased number of live pups per litter in rats . . . and mice . . . , reduced growth in rats . . . and mice . . . , and delayed puberty in male mice . . . male rats . . . and female rats . . . ." (Italics added.)

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[5] The monograph explains that "[s]cientific decisions concerning health risks are generally based on what is known as the 'weight of the evidence.' " Figure 2b of the monograph sets forth the "weight of evidence that [BPA] causes adverse developmental or reproductive effects in laboratory animals," rated along the following continuum: "Clear evidence of adverse effects"; "Some evidence of adverse effects"; "Limited evidence of adverse effects"; "Insufficient evidence for a conclusion"; "Limited evidence of no adverse effects"; "Some evidence of no adverse effects"; "Clear evidence of no adverse effects." In tests involving " 'High' dose developmental toxicity," the monograph indicated that there was "[c]lear evidence of adverse effects." In tests involving reproductive toxicity, the monograph indicated that there was "[s]ome evidence of adverse effects." In tests involving " 'Low' dose developmental toxicity," the monograph indicated that there was "[l]imited evidence of adverse effects." As we discuss *post*, OEHHA relied on the "high" dose findings in determining BPA had been identified by NTP as a reproductive intoxicant [notice of intent to list based on "clear evidence of adverse developmental effects in laboratory animals at 'high' levels of exposure"].)

The monograph further stated that there was scientific controversy over interpretation of " 'low' dose findings" in animals. It stated that, in "addition to the[] 'high' dose effects on survival and growth, the NTP recognizes that there are studies that provide evidence for a variety of effects at much lower dose levels of [BPA] related to neural and behavioral alterations in rats and mice . . . , preneoplastic lesions in the prostate and mammary gland in rats . . . , altered prostate and urinary tract development in mice . . . , and early onset of puberty in female mice . . . ." The monograph stated that "[t]hese 'low' dose findings in laboratory animals have proven to be controversial for a variety of reasons including concern for insufficient replication by independent investigators, questions on the suitability of various experimental approaches, relevance of the specific animal model used for evaluating potential human risks, and incomplete understanding or agreement on the potential adverse nature of reported effects."

The monograph stated that there was "[i]nsufficient evidence for a conclusion" as to whether BPA had adverse developmental or reproductive effects in humans. The monograph further explained, "evidence from the limited number of studies in humans exposed to [BPA] is not sufficient to reach conclusions regarding possible developmental or reproductive hazard." However, it also said: "Recognizing the lack of data on the effects of [BPA] in humans and despite the limitations in the evidence for 'low' dose effects in laboratory animals . . . , *the possibility that [BPA] may alter human development cannot be dismissed*." (Italics added.)

Addressing the "very small number of studies [that] have looked at associations between [BPA] exposure and disorders of reproduction or developmental effects in humans," the monograph stated that "there is currently insufficient evidence to determine if [BPA] causes or does not cause reproductive toxicity in exposed adults," and that there "is also insufficient evidence from studies in humans to determine if [BPA] does or does not cause developmental toxicity when exposure occurs prenatally or during infancy and

childhood." However, the monograph stated that the scientific literature on the toxic effects of BPA in laboratory animals was "extensive and expanding."

Turning to the question whether current exposures to BPA are high enough to be cause for concern, the monograph concluded: "[*p*]*ossibly*." The monograph stated that the " 'high' dose effects of [BPA] in laboratory animals that provide clear evidence for adverse effects on development, i.e., reduced survival, birth weight, and growth of offspring early in life, and delayed puberty in female rats and male rats and mice, are observed at levels of exposure that far exceed those encountered by humans." The monograph continued: "[E]stimated exposures in pregnant women and fetuses, infants, and children are similar to levels of [BPA] associated with several 'low' dose laboratory animal findings of effects on the brain and behavior, prostate and mammary gland development, and early onset of puberty in females. When considered together, these laboratory animal findings provide limited evidence that [BPA] has adverse effects on development." The monograph then stated: "The conclusion of similarities between exposures of certain human populations and laboratory animals treated with 'low' doses of [BPA] is supported by multiple approaches. For this reason, *the possibility that human development may be altered by [BPA] at current exposure levels cannot be dismissed*." (Italics added.)

In a section entitled "NTP CONCLUSIONS," the monograph stated that the NTP "reached the following conclusions on the possible effects of exposure to [BPA] on human development and reproduction. Note that the possible levels of concern, from lowest to highest, are negligible concern, minimal concern, some concern, concern, and serious concern. [¶] The NTP has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to [BPA]. [¶] . . . [¶] The NTP has *minimal concern* for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children at current human exposures to [BPA]. [¶] . . . [¶] The NTP has *negligible concern* that exposure of pregnant women to

[BPA] will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring. [¶] . . . [¶] The NTP has *negligible concern* that exposure to [BPA] will cause reproductive effects in non-occupationally exposed adults and *minimal concern* for workers exposed to higher levels in occupational settings." (Boldface omitted.)

DART-IC Meeting and Determination

DART-IC held a meeting on July 15, 2009, to consider action on BPA. The DART-IC considered the monograph, among other things. Following the staff presentations and public comment, the DART-IC held its discussion.

One of the committee members specifically charged with reviewing the issue of developmental toxicity stated that "[t]he high dose studies have clear evidence of developmental toxicity," in animals, although she continued: "They do occur in the presence of maternal toxicity. It's whether or not there is sufficient maternal toxicity to potentially be causing the other." As for the low-dose animal studies, she stated that "there are not clear effects on the low-dose levels, because we have seen situations where some studies are positive and some studies are negative. And when you do have very small numbers of animals in groups, that does increase the variability within a group." Another committee member stated, "I'm not so sure that . . . the animal model can extrapolate into the human model, because the doses were so incredibly high. There were very high doses that we would not expect humans to be exposed to."

At the conclusion of the discussion, the DART-IC voted on the following questions: "has [BPA] been clearly shown, through scientifically valid testing, according to generally accepted principles, to cause" (1) developmental toxicity, (2) female reproductive toxicity, and (3) male reproductive toxicity. As to each question, the DART-IC members voted no and accordingly voted against listing BPA. Following the vote, the DART-IC did not articulate any specific bases for its determinations against

listing BPA, although the simple "no" answers to questions asking whether "[BPA] been clearly shown . . . ." indicated a finding that a clear showing had not been made.

NRDC Petitions

The NRDC sent to OEHHA petitions dated July 15 and 21, 2009, requesting that OEHHA list BPA under Proposition 65 as a chemical known to cause reproductive toxicity because it had been identified as a reproductive toxicant by an authoritative body, specifically NTP-CERHR.

OEHHA Request for Information and Public Forum

OEHHA issued a statement indicating that it had received the NRDC's petition and noting that DART-IC had declined to list BPA as a reproductive toxicant under the state's qualified experts listing mechanism of section 25249.8. The OEHHA statement observed that each of the four listing mechanisms established in section 25249.8 (see fn. 2, *ante*) was separate and distinct, none of which takes precedence over the others. Consequently, according to OEHHA, it was required to consider listing BPA under the authoritative body listing mechanism regardless of the DART-IC determination. OEHHA stated that the monograph "concludes that [BPA] causes developmental toxicity at high levels of exposure, and appears to satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations. [¶] OEHHA is relying on the NTP-CERHR's conclusions in the report that BPA causes reproductive toxicity. The NTP-CERHR report concludes that there is clear evidence of adverse developmental effects in laboratory animals at 'high' levels of exposure." The OEHHA statement concluded: "Based on the NTP-CERHR report and the references cited in the report, the evidence appears sufficient for listing by the authoritative bodies' mechanism."

OEHHA announced a public forum scheduled for April 20, 2010, at which anyone could present scientific data and other information relevant to whether BPA met the criteria for listing under California Code of Regulations, title 27, section 25306, which

describes the authoritative body mechanism.[6] A number of participants offered their opinions at the forum, both in opposition to and in favor of listing BPA.

Included among those who did not favor listing BPA was Dr. Rochelle Tyl, the author of four of the eight high dose studies discussed in the monograph. Dr. Tyl stated: "Based on my intimate knowledge of these [high dose] studies and my review of other relevant studies, I conclude that BPA is not a selective reproductive or developmental toxicant. [R]eproductive or developmental effects occur only at very high BPA doses in the presence of profound maternal toxicity. At lower doses with less, but still significant, maternal toxicity, there are no reproductive or developmental effects. Based on other relevant studies, it is apparent that maternal toxicity is most likely the critical determinant of embryo-fetal/offspring toxicity observed at high doses of BPA. Consequently, BPA does not satisfy the criteria for listing under Proposition 65."

DART-IC Consideration of NTP's Designation as an Authoritative Body

ACC filed a petition seeking rescission of NTP-CERHR's designation as an authoritative body "for purposes of developmental reproductive identifications." On July 12, 2011, DART-IC considered the designation of the NTP as an authoritative body. During the meeting, an attorney for ACC clarified during public remarks that the petition was "retrospective with respect to monographs that were published by the previously existing NTP CERHR," which had purportedly undergone changes in the interim. A representative of the NRDC asserted that BPA "has really driven much of this discussion." The attorney for ACC stated that the petition was filed "because of the anomaly that came to our attention after the BPA decision two years ago. [Y]our Committee voted 7 to nothing, unanimously on all three toxicity endpoints to determine that BPA should not be listed as a reproductive toxicant. [¶] That very day a petition

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[6] Further undesignated references to regulations are to title 27 of the California Code of Regulations.

was submitted asking the chemical to be listed versus [*sic*] the authoritative bodies mechanism. . . . [T]he agency is actively considering listing the same chemical under the authoritative bodies mechanism on the basis of the same document that you reviewed so carefully and so thoroughly, with days of testimony talking in person to the people who conducted those studies, to determine whether or not the document, on its face, either concludes that BPA is a developmental toxicant or that it otherwise identifies the chemical as a reproductive toxicant. [¶] We think . . . that means if those two things can happen on the same day and on the basis of the same document, something is seriously wrong. . . . [I]t's a question of how this document can be used productively and whether it can be used productively, consistently, and authoritatively to be served as the authoritative bodies listing, or conversely, maybe whether it's not, and instead it should be considered by you in a forum where you have the freedom to delve down into the data and make a decision based on the data."

Ultimately, none of the DART-IC members voted in favor of rescinding NTP-CERHR's designation as an authoritative body and five members voted against doing so.

OEHHA Notice of Intent to List BPA

On January 24, 2013, OEHHA issued a notice of intent to list BPA on the Proposition 65 list of chemicals known to cause reproductive toxicity. In an attachment, OEHHA explained that "[u]nder the Proposition 65 regulations, a chemical must be listed via the authoritative bodies mechanism when two conditions are met: 1) An authoritative body formally identifies the chemical as causing reproductive toxicity ([Regulation] 25306(d)) [and] 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations ([Regulation] 25306(g))." OEHHA specified that its decision to list BPA was based on the finding of NTP-CERHR that BPA caused developmental toxicity in laboratory animals at high levels of exposure. According to OEHHA, the NTP-CERHR monograph "satisfie[d] the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations."

ACC's Complaint and Writ Petition

As a result of the OEHHA's notice of intent, ACC commenced this action by filing a verified complaint in the trial court on March 1, 2013, seeking to enjoin OEHHA from adding BPA to the Proposition 65 list as a reproductive toxicant on the basis of the monograph. ACC asserted that the monograph did not "formally identify" BPA as causing reproductive toxicity, but instead only concluded that the " 'possibility that [BPA] may alter human development cannot be dismissed,' and that 'studies in laboratory animals provide only limited evidence for adverse effects on development and more research is needed to better understand their implications for human health.' " ACC also asserted that OEHHA's determination to list BPA was contrary to the determination of DART-IC, which unanimously concluded that BPA should not be listed based on its review of the same monograph as well as the underlying studies. ACC emphasized that the monograph specifically stated that the " 'weight of evidence that [BPA] causes adverse developmental or reproductive effects in humans' is '*insufficient evidence* for a conclusion.' "

ACC went on to contend that OEHHA's determination to list BPA was an abuse of discretion, exceeded OEHHA's authority, and was contrary to law. Specifically, ACC asserted: (1) OEHHA's notice of intent to list did not satisfy its own regulations because it did not allege that the monograph concluded that an association between adverse reproductive effects in humans and BPA is biologically plausible as required by Regulation 25306, subdivision (g)(2); (2) the monograph did not formally identify BPA as causing reproductive toxicity, as required under section 25249.8, subdivision (b), but instead merely contained intermediate references to studies of mice and rats which OEHHA treated as formal identification; (3) OEHHA's conclusion that the monograph constituted formal identification of BPA as a reproductive toxicant based solely on studies showing adverse effects in laboratory animals at high doses was contrary to, and in fact precluded by, the conclusion of DART-IC, the state's qualified experts who

reviewed the same monograph and its underlying studies and voted that BPA should not be listed; and (4) subsequent studies had superseded any conclusion that BPA caused reproductive toxicity, and therefore OEHHA's regulations required a finding that BPA did not satisfy the definition of "as causing reproductive toxicity" (Regs. § 25306, subd. (h)), and OEHHA abused its discretion in failing to consider the subsequent studies and/or by not finding that they precluded the listing of BPA.

ACC complained that, if not enjoined, the listing of BPA pursuant to Proposition 65 would cause immediate and irreparable harm and, conversely, OEHHA would suffer no harm if the listing of BPA was delayed. ACC also asserted that it had either exhausted all available administrative remedies or was excused from doing so based on futility, irreparable harm, or the administrative agency's lack of jurisdiction to proceed.

In the first cause of action, ACC sought declaratory relief, declaring its rights and OEHHA's duties under Government Code section 11350, subdivision (a), and Code of Civil Procedure section 1060. In the second cause of action, ACC sought preliminary and permanent injunctive relief, enjoining OEHHA from adding BPA to the Proposition 65 list of chemicals known to the State of California to cause reproductive toxicity. ACC asserted that it had no adequate remedy at law.

On March 27, 2013, ACC filed a motion for a preliminary injunction, seeking to enjoin OEHHA from listing or taking any further action in listing BPA as a reproductive toxicant under Proposition 65 pursuant to the authoritative body listing mechanism. (Regs. § 25306.)

In an amended complaint, ACC added a cause of action seeking a peremptory writ of mandate pursuant to Code of Civil Procedure section 1085, directing OEHHA to take all necessary steps to halt the listing of BPA and directing OEHHA not to list BPA pursuant to Proposition 65.

OEHHA Lists BPA and the Trial Court Grants ACC a Preliminary Injunction

After ACC commenced this action, and after it filed its motion for a preliminary injunction, OEHHA published notice, effective April 11, 2013, stating that it was adding BPA to the list of chemicals known to the State of California to cause reproductive toxicity. OEHHA then filed a notice in the trial court stating that ACC's case had been rendered moot as a result of its listing of BPA pursuant to Proposition 65.

In oral argument on ACC's motion for a preliminary injunction, OEHHA explained that there are two steps in the process under Proposition 65. In the first step, the agency determines the type of hazard posed by the subject chemical, such as whether it is a carcinogen or a reproductive toxin. In the second step, the agency determines what the concern is for humans being affected by that hazard. OEHHA argued that chemicals are listed on the Proposition 65 list based on the first step only. In other words, if the chemical poses a particular hazard, such as being a carcinogen or causing developmental toxicity, the chemical is added to the list even if the evidence of the hazard posed relates to animal studies, so long as the "evidence is sufficient and meets the criteria."

OEHHA asserted that chemicals that are found to be animal toxins are listed because scientists presume that chemicals which cause harm in animals will also cause harm in humans. OEHHA stated that hazard identification is "almost always based on animal studies, because you can't feed the chemical to humans -- and it identifies the hazard."

OEHHA characterized the monograph as stating, in substance: "we don't have enough evidence to know what the effect is in humans; we can't tell you what the problems are in humans, but we do know that this chemical is a developmental toxin in animals and we have some concern in humans, some concern for infants exposed to the chemical at the current levels of exposure . . . ." OEHHA emphasized that the monograph stated repeatedly that there was clear evidence of developmental toxicity in animals. OEHHA argued: "they said it in five or six different places in different

phrasing, but they kept saying, clear evidence of developmental toxicity in animals. [¶] That's the identification of the hazard, developmental toxicity. That's what OEHHA looks to, it doesn't look at the risk to humans at that point." However, OEHHA does not merely accept the NTP's position that the subject chemical poses a particular hazard; "it has to dig deeper." The OEHHA scientists review the studies and NTP's analysis, and OEHHA independently reaches its conclusion as to whether NTP was correct that the subject hazard is indeed present. OEHHA further reviews whether it is biologically plausible that the chemical presents the same hazard, and will cause the same effects, in humans.

The trial court interposed that, given the DART-IC determination that BPA need not be listed, there appeared to be a significant scientific dispute as to whether BPA should indeed be published on the Proposition 65 list. The trial court repeatedly expressed concern about the time lapse of several years since the publication of the monograph, and yet OEHHA was suddenly "rushing to list it when you get a lawsuit filed."

OEHHA responded that it and the DART-IC, which operate under different listing mechanisms, approach their review of the NTP findings differently. DART-IC essentially reviews all of the evidence and considers the matter de novo. Conversely, OEHHA reviews the NTP findings and considers whether those findings meet the criteria for listing. According to OEHHA, it "must still list it if it meets the criteria based on their review of the NTP and [OEHHA's] inability to substitute their own decision; they have to accept what the NTP did as long as it meets the criteria in the statute, in the regulations. So it's a very different proceeding."

ACC emphasized that the DART-IC had considered the same monograph and unanimously voted against listing BPA. On the same day, NRDC petitioned OEHHA for the listing of BPA under the authoritative body listing mechanism. OEHHA chose to act on the NRDC petition, but three years passed before it issued the notice of intent to list.

Thus, for purposes of the trial court's consideration of ACC's motion for a preliminary injunction, ACC asserted that this timeline demonstrated that there was "no rush whatsoever here."

ACC emphasized that, for listing under the authoritative body listing mechanism, there had to be a finding by OEHHA that the authoritative body had made its formal identification of the chemical "in conformity with the criteria that require[] that there be sufficient data to show a biologically plausible association between the chemical and the -- an adverse effect in humans." ACC maintained that there was no formal identification in the monograph that BPA was a reproductive toxicant. It emphasized the language in the monograph which stated: "despite the limitations in the evidence for low dose effects in laboratory animals . . . the possibility that [BPA] may alter human development cannot be dismissed." ACC also emphasized the monograph language stating: " 'Overall, the current literature cannot yet be fully interpreted for biological or experimental consistency or for relevance to human health,' " and " '[a]dditional research is needed to understand the metabolism of [BPA] in both laboratory animals and humans.' " ACC suggested that this language did not amount to the formal identification of a chemical that would warrant listing.

ACC further noted that OEHHA's intent to list was solely based on high dose studies, and "the NTP, with respect to the high dose studies, had only minimal or negligible concern with respect to any risk for humans." ACC further asserted that, inasmuch as OEHHA was "acting contrary to the state's gubernatorially appointed scientific experts, that is also an abuse of discretion."

In reply, OEHHA asserted that the ACC was "mixing apples and oranges. [D]iscussions about the risks to humans are not the identification, it's the clear evidence of developmental effect that's at issue here." OEHHA further asserted that, as stated in case law, the NTP need not make a particular statement, or, in other words, use particular

terminology; OEHHA must look at the monograph and determine whether the "correct identification in the findings were made."

The trial court granted ACC's motion for a preliminary injunction, directing OEHHA to immediately remove BPA from the Proposition 65 list. Thereafter, OEHHA issued a notice announcing that BPA was delisted.

NRDC Intervenes

On June 18, 2013, the trial court granted NRDC's motion to intervene as a party defendant.

Hearing in the Trial Court

At the beginning of the hearing, ACC asserted that "the State of California of Scientists [*sic*], the DART-IC, and every governmental organization worldwide that's evaluated BPA has considered it safe for humans." ACC then asserted that the "erroneous" listing of BPA would cause significant harm, both to ACC and to the public.

ACC argued that there was no formal identification and emphasized that the monograph only concluded that "the possibility that BPA may alter human development cannot be dismissed." According to ACC, that statement amounted to a conclusion that NTP could not say that BPA is a reproductive toxicant. ACC asserted that this conclusion—that the NTP could not dismiss the possibility that BPA may alter human development—is irreconcilable with the conclusion that the NTP had formally identified BPA as a reproductive toxicant. ACC asserted that the contrast in the language between what the NTP used in other briefs when it has formally identified a chemical as a reproductive toxicant and the monograph on BPA here was "quite dramatic" and "striking." For example, for a different chemical, the monograph stated: "[T]he NTP judges the scientific evidence of the effect on laboratory animals sufficient to conclude that [the chemical] may adversely affect human development and reproduction if exposures are sufficiently high." Based on this, ACC contended that the NTP knew how

to state that a chemical is or may be a developmental toxicant, and it had not done so here.

ACC also emphasized the low levels of concern expressed in the monograph. Given that the monograph for the most part stated that the NTP had negligible or minimal concern in most areas, ACC asserted that it could not reasonably be concluded that the monograph constituted a formal identification of BPA as a reproductive toxicant.

ACC further asserted that, under the regulations, to warrant listing BPA, the data had to show that it was biologically plausible that the adverse reproductive effects will occur in humans. Thus, according to ACC, animal data alone is insufficient to establish reproductive toxicity. Instead, there had to be a conclusion that it was biologically plausible that those effects seen in experimental animals will occur in humans.

ACC characterized the monograph as "replete with concerns about the ability to translate the animal data to human effects." Therefore, according to ACC, there was no leeway for OEHHA to maintain it was biologically plausible that the effects found in animals would occur in humans. ACC maintained a statement that NTP could not dismiss the possibility that BPA may alter human development does not constitute a finding that those effects are biologically plausible in humans.

ACC further argued that there was no other evidence in the administrative record of biological plausibility. Addressing what OEHHA referred to as a presumption of biological plausibility, ACC asserted that OEHHA had "not submit[ed] anything that suggest[s] why there is biological plausibility in this case other than saying, 'We assume that the results of animal data apply to humans.' " However, according to ACC, OEHHA's own regulations require that there be a determination based on various factors indicating biological plausibility in humans.

ACC also contended that the statement in the monograph that "high dose studies are not controversial and provide clear evidence of adverse effects on development in laboratory animals," was not offered as a conclusion in that section. According to ACC,

the question posed in that section of the monograph was: "Can [BPA] affect human development reproduction?" ACC asserted that the statement concerning the high dose studies was not intended to answer that question, but instead "indicat[ed] that this is some data that it's considering," and was noting that this information was derived using "hugely excessive" dosage levels.

ACC also emphasized that the monograph stated that there was scientific controversy as to the lower dose findings. According to ACC, when considered together, the high dose and low dose studies "provide[] limited evidence of adverse effects."

ACC then asserted that it was an abuse of discretion for OEHHA to disregard the 2009 DART-IC declination. ACC emphasized that the attorney for the NRDC advanced the same arguments before OEHHA that it had earlier made before the DART-IC, and the DART-IC rejected those arguments. According to ACC, the DART-IC "made express[] statements that they didn't think that the effects in the high dose studies could be extrapolated to humans." ACC asserted that OEHHA should not be permitted to list BPA given what the DART-IC stated about the inability to use the high dose studies as a basis for listing BPA.

OEHHA emphasized the deferential standard of review to be accorded to it in a case such as this, involving highly technical record addressing scientific material. It then asserted that "[a] lot of ACC's argument hinges on its confusion between hazard identification and risk." Hazard identification refers to the inquiry into what harm a chemical causes, such as reproductive toxicity or developmental toxicity. Risk, on the other hand, is related to how much people are exposed to the chemical and how real the threat to people is. OEHHA asserted that ACC "keeps . . . muddling the concepts here and trying to confuse the hazard identification with the level of concern or the risk."

OEHHA asserted that, while the monograph stated that there was insufficient evidence from humans to draw a conclusion, this circumstance was actually common. OEHHA argued there are very few chemicals for which there is "sufficient human

evidence" because "we don't do experiments on humans." Therefore, scientists generally have to consider animal evidence.

In the hazard identification stage, according to OEHHA, NTP concluded that there was limited evidence of developmental toxicity in low dosages, and evidence of adverse effects of reproductive toxicity. OEHHA acknowledged, however, that neither of these findings would be sufficient to support listing BPA because limited evidence and some evidence is not enough. However, the monograph also stated that there was clear evidence of adverse effects of developmental toxicity in high dosages. OEHHA stated that this was what it considered in the monograph, which was identical to what it considered in all other NTP monographs it had reviewed. OEHHA also emphasized the language in the monograph stating that the high dose effects were not considered scientifically controversial and provided clear evidence of adverse effects on development in laboratory animals. The monograph further stated that the NTP found "clear evidence of adverse developmental hazards at high doses of" BPA. OEHHA stated that the foregoing statements constituted the hazard identification, and this is what OEHHA considers in determining whether or not to list a chemical.

OEHHA again argued that ACC's focus on the level of concern portions of the monograph was not "relevant to the listing here, because that is the risk assessment portion. That is what's telling us whether people are exposed to the chemical and if so, should we be worried about it. [I]t's a clear hazard, a clear developmental hazard, but we are going to have negligible concern because people don't get exposed to the chemical."

OEHHA acknowledged that the analysis for listing does not end with the identification. After identifying the hazard, OEHHA must determine whether the studies relied upon were sufficient to indicate that it is biologically plausible that the chemical will cause harm in humans. According to OEHHA, biological plausibility is a technical term that does not refer to exposure or level of concern. Rather, it refers to the determination of "whether it's appropriate to extrapolate from animals to humans," a

question that arises with virtually all animal studies. OEHHA stated that, as a general principle, in the absence of evidence to the contrary, it is proper to assume that a chemical that causes harm in animals will cause harm in humans. According to OEHHA, the general presumption, which is supported by *Exxon Mobil, supra,* 169 Cal.App.4th 1264, is that, absent evidence to the contrary, "you always make this extrapolation and that is what constitutes the biological plausibility." As an example of a circumstance indicating biological plausibility is *not* present, OEHHA referenced a situation when the animal has a particular physical structure that is harmed but that physical structure is not present in humans. Another example would be when there is evidence the animal metabolizes the chemical differently than humans. OEHHA argued, "absent that evidence, the normal assumption is that you always make this extrapolation and that is what constitutes the biological plausibility."[7]

OEHHA argued that *Exxon Mobil* made clear that the monograph does not have to explicitly say anything about biological plausibility and there is "no magic language . . . that a report would have to use. The real responsibility is on OEHHA to look at the underlying studies, to make sure that they are adequate, to make sure that there is no evidence to the contrary that would indicate it's not appropriate to extrapolate from animals to humans and to determine biological plausibility." OEHHA asserted that biological plausibility is a scientific term that calls not for determining plausibility in a

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[7] OEHHA's argument was consistent with the response it offered to comments in the administrative process. There, OEHHA wrote: "There is no requirement that developmental or reproductive effects have actually been demonstrated in humans. Although the biological plausibility that effects could occur in humans is considered under the criteria in [Regulation] 26306(g), it is a fundamental assumption of toxicology that the results of toxicity testing of chemicals in animal models are indicative of potential effects in humans. [¶]…[¶] [I]n the absence of convincing data that effects are not plausible in humans because of metabolic, physiologic or other biological considerations, it is assumed that a chemical that causes developmental toxicity in an animal model may do so in humans."

"lay sense," but rather in a "technical sense." It is "appropriate to extrapolate, and the rule is that you do so unless there is evidence to the contrary. So by stating 'possibly,' NTP was in effect indicating we have not seen any evidence to the contrary that would lead us to refute the normal toxicological principle that permits you to extrapolate . . . from animals to humans."

Here, however, OEHHA stated that the monograph did contain a statement about biological plausibility. In response to the question, " 'Can [BPA] affect human development or reproduction?' " The report answered, "possibly." According to OEHHA, this, in itself, is a statement of biological plausibility. OEHHA argued, "it's . . . easy to confuse lay terms and lay meanings and to say '. . . possible doesn't mean plausible.' But we are dealing with a technical scientific term. We're not dealing with a lay term as to what is plausible." The scientific term biological plausibility is an extrapolation. "Clearly the NTP believed that it was appropriate to extrapolate from animals to humans and that there was not counter evidence." According to OEHHA, the NTP's statement that the possibility that BPA may alter human development cannot be dismissed is essentially the same as saying biological plausibility cannot be rejected.

Regarding the different language used in other NTP reports, OEHHA noted that instead of saying the NTP "judges the evidence sufficient" to conclude [BPA] can cause reproductive toxicity in humans, the report said that the NTP "can't omit the possibility that this could cause harm in humans." According to OEHHA, this "formulation actually means the same thing. In both cases the NTP is saying, 'we can't reject biological plausibility. We have to go with the normal toxicological assumption.' "

OEHHA asserted that, in any event, NTP did not have to say anything about biological plausibility because it was OEHHA's responsibility to determine whether there was biological plausibility and whether it would be appropriate to extrapolate. OEHHA reviewed the studies and determined they " 'don't demonstrate a lack of biological

plausibility.' " There was no evidence to " 'refute biological plausibility and that would lead [OEHHA] not to extrapolate from animals to humans.' "

The Trial Court's Ruling

The trial court denied the relief requested in the amended complaint. The court rejected the premise that, to support listing under Proposition 65, there must be clear evidence that a chemical is known, not merely suspected, to cause cancer or reproductive toxicity *in humans*, noting that this court had rejected that argument in *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425 (*Deukmejian*). The trial court reasoned that Proposition 65 is not limited to chemicals known to cause cancer or reproductive toxicity *in humans*, and the omission of any such limitation implies that chemicals are to be listed even if they are known to cause cancer or reproductive toxicity only *in animals*. The court recognized that because of the difficulties in making determinations through studies involving humans, extrapolation from animal testing is widely accepted as both justifiable and necessary. Thus, Proposition 65 applies to chemicals determined to cause cancer or reproductive toxicity in humans or animals. The trial court stated that the operative question for listing a chemical under Proposition 65 is not whether it is probably carcinogenic or toxic to humans, but rather whether it is a known carcinogen or reproductive toxin.

The trial court stated that "the [m]onograph involves a two-phase process. In [p]hase 1, the hazard identification phase, the [m]onograph assesses the scientific evidence to determine whether a substance causes adverse effects on reproduction and development. In [p]hase 2, the [m]onograph reviews the data and expresses a 'level of concern' for humans based on current levels of exposure to the chemical."[8] The trial court reasoned that ACC's contention that NTP found insufficient evidence to conclude

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[8] We note that it is not the monograph that involves a two-step process. Rather, as we discuss *post*, it is Proposition 65 that sets out a two-step process.

that BPA is a reproductive toxicant was based on statements addressed to the phase 2 analysis. However, the monograph, in its phase 1 analysis, found there to be "clear evidence" of adverse developmental effects in laboratory animals administered high doses of BPA. The trial court concluded that this was "sufficient to satisfy the hazard identification phase of the regulatory listing requirements."

The trial court also rejected ACC's contention that OEHHA abused its discretion in finding that there was sufficient evidence to conclude that an association between adverse reproductive effects in humans and BPA was "biological[ly] plausible." (Regs. § 25306, subd. (g).) Concluding that ACC misconstrued the meaning of "biological plausibility," the trial court stated that "[b]iological plausibility is not concerned with the level of exposure to a chemical or the level of concern to humans from such exposure; it is concerned with whether adverse effects reported in animal studies reasonably can be extrapolated to humans." Therefore, according to the trial court, the NTP's conclusion that there was "negligible" or "minimal" concern to humans for certain adverse effects at current levels of exposure did not necessarily preclude a finding of biological plausibility.

The trial court found that OEHHA interpreted its regulation's biological plausibility requirement based on the holding in *Exxon Mobil, supra* 169 Cal.App.4th 1264. Consistent with *Exxon Mobil,* OEHHA interprets biological plausibility to mean that, absent evidence to the contrary, effects observed in laboratory animals are assumed to be subject to extrapolation in humans. The trial court emphasized that the *Exxon Mobil* court upheld this assumption notwithstanding the fact that the authoritative body in that case did not explicitly discuss whether the findings as to animals were relevant to humans. (*Id*. at pp. 1287-1288.) The trial court read *Exxon Mobil* to suggest that extrapolation from animals to humans is inappropriate only where evidence shows that experimental animals differ in physiologically significant ways from humans. Thus, according to the trial court, the *Exxon Mobil* court approved of a " 'generally accepted toxicological assumption' that, absent evidence to the contrary, a chemical that causes

developmental harm in experimental animals, will cause similar harm in humans." (*Id*. at p. 1289.) The trial court concluded that OEHHA did not abuse its discretion by following that principle in this case. Nor did it abuse its discretion by finding that NTP formally identified BPA as causing reproductive toxicity within the meaning of Proposition 65.

The trial court further ruled that OEHHA did not abuse its discretion by disregarding the state's qualified experts, DART-IC. The court agreed with OEHHA that the DART-IC's determination against listing BPA under the state's qualified experts listing mechanism did not preclude OEHHA from listing it under the separate authoritative body listing mechanism. These listing mechanisms are separate and independent, and DART-IC's determination under one is not controlling of the other. Rather, if the listing requirements are met for the authoritative body mechanism, OEHHA is mandated under the law to list a chemical even where the state's qualified experts have declined to do so. And because the authoritative body listing mechanism is separate and independent from the qualified experts mechanism, the court reasoned that OEHHA was not required to consider DART-IC's opinion. However, the court went on to note that the record showed OEHHA did, in fact, consider that opinion.

Finally, the trial court determined that OEHHA did not abuse its discretion by disregarding the opinion of Dr. Tyl, who opined that BPA does not satisfy the criteria for listing under Proposition 65. The trial court stated that Dr. Tyl's opinion was not binding on OEHHA, and OEHHA's determination that her opinion was not persuasive was within its discretion.

The trial court denied all relief requested by ACC in the amended complaint. It also denied ACC's request for a stay pending appeal, although it left in place the preliminary injunction until the expiration of ACC's time to file a notice of appeal, thus affording ACC the opportunity to file a petition for a writ of supersedeas.

Motion for New Trial and Judgment

Later, the trial court denied ACC's motion for a new trial. Thereafter, the court entered judgment, denying ACC all relief requested in the amended complaint in accordance with its prior ruling. The court again indicated that it would stay the judgment and keep the previously entered preliminary injunction in place until the expiration of the time for filing a notice of appeal to allow ACC the opportunity to file a petition for a writ of supersedeas.

Stay Pending Appeal

Another panel of this court construed ACC's "Petition for Writ of Supersedeas or Other Extraordinary Relief" to be a request for a stay pending appeal, granted that request, and directed that the stay shall remain in effect pending further order of this court.

DISCUSSION

I. Standards of Review

A. Writ of Mandate

"In determining whether to grant a petition for traditional mandamus, we review for an abuse of discretion. ' " 'Abuse of discretion is established if the respondent [agency] has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence.' [Citations.]" [Citation.]' [Citation.] 'In determining whether the agency complied with the required procedures and whether the agency's findings are supported by substantial evidence, the trial court and the appellate courts essentially perform identical roles. We review the record de novo and are not bound by the trial court's conclusions.' " (*Exxon Mobil, supra,* 169 Cal.App.4th at p. 1276.)

We further note that "[i]n a mandate proceeding, the party seeking the writ must show a clear and present duty of the respondent to act in conformity with the proposed writ." (*Western Crop Protection Association v. Davis* (2000) 80 Cal.App.4th 741, 757

(*Western Crop*).) Thus, as the party seeking a judicial remedy, ACC bears the burden of showing OEHHA's listing under Proposition 65 is inconsistent with law. (*Ibid*.)

B. Declaratory and Injunctive Relief

A complaint seeking declaratory and injunctive relief may also be an appropriate means by which to challenge OEHHA's listing of a chemical on the Proposition 65 list. (See *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 1082 (*Styrene*).) The decision to grant or deny injunctive relief is generally reviewed by the appellate court under the abuse of discretion standard (*Salazar v. Eastin* (1995) 9 Cal.4th 836, 849-850), as is the decision to deny a request for declaratory relief (*County of Los Angeles v. California State Water Resources Control Bd.* (2006) 143 Cal.App.4th 985, 997-998). "However, to the extent our review involves basic questions of statutory and regulatory interpretation, we review those questions of law de novo." (*Californians for Pesticide Reform v. California Dept. of Pesticide Regulation* (2010) 184 Cal.App.4th 887, 899.) Additionally, "to the extent the trial court had to review the evidence to resolve disputed factual issues, and draw inferences from the presented facts, an appellate court will review such factual findings under a substantial evidence standard." (*Shapiro v. San Diego City Council* (2002) 96 Cal.App.4th 904, 912.)

C. Review of Government Agency Interpretations of Regulations

"As a general matter, courts 'will be deferential to government agency interpretations of their own regulations, particularly when the interpretation involves matters within the agency's expertise and does not plainly conflict with a statutory mandate. [Citation.] . . . [W]e will not disturb the agency's determination without a demonstration that it is clearly unreasonable.' [Citation.] While final responsibility for interpreting a statute or regulation rests with the courts and a court will not accept an agency interpretation that is clearly erroneous or unreasonable, ' "[a]s a general rule, the courts defer to the agency charged with enforcing a regulation when interpreting a

regulation because the agency possesses expertise in the subject area." ' " (*Exxon Mobil, supra*, 169 Cal.App.4th at pp. 1276-1277.)

At issue in this case is whether OEHHA's listing of a chemical comports with section 25249.8 and the regulations promulgated thereunder. "In considering this issue, the scope of our review ' "is limited, out of deference to the agency's authority and presumed expertise: 'The court may not reweigh the evidence or substitute its judgment for that of the agency. [Citation.]' " [Citation.] "In general . . . the inquiry is limited to whether the decision was arbitrary, capricious, or entirely lacking in evidentiary support . . . ." [Citation.] When making that inquiry, the " ' "court must ensure that an agency has adequately considered all relevant factors, and has demonstrated a rational connection between those factors, the choice made, and the purposes of the enabling statute." [Citation.]' " [Citation.]' [Citation.] This limited judicial review is further constrained by the recognition that ' "[i]n technical matters requiring the assistance of experts and the study of marshaled scientific data as reflected herein, courts will permit administrative agencies to work out their problems with as little judicial interference as possible." ' " (*Exxon Mobil, supra*, 169 Cal.App.4th at p. 1277.) We discuss in more detail *post* rules applicable to the regulation at issue here.

II. Proposition 65 - Statutory and Regulatory Scheme

A. Proposition 65

Proposition 65, adopted in 1986, was intended to protect people and the water supply from harmful chemicals. (*Deukmejian, supra*, 212 Cal.App.3d at p. 429.) "The initiative . . . imposes severe penalties upon those who contaminate drinking water with carcinogenic and toxic chemicals and who expose individuals to such chemicals without warning." (*Id*. at p. 430.)

Proposition 65 added sections 25249.5 through 25249.13 to the Health and Safety Code. (*Exxon Mobil, supra*, 169 Cal.App.4th at p. 1268; *Deukmejian, supra*, 212 Cal.App.3d at p. 429.) It applies only to those chemicals "that have been identified and

listed as chemicals 'known to the state to cause cancer or reproductive toxicity.' " (*Deukmejian*, at p. 431, quoting § 25249.5.) Therefore, the identification and listing of those chemicals as such "are pivotal to the entire statutory scheme." (*Deukmejian*, at p. 431.)

Section 25249.8, subdivision (a), requires the Governor to publish "a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter," and to have the list revised and republished at least annually. A review of the chemicals listed pursuant to Proposition 65 reveals that, when a chemical is listed as known to cause reproductive toxicity, the listing specifies which endpoint was implicated: male reproductive toxicity, female reproductive toxicity, and/or developmental toxicity. (Regs. § 27001, subd. (c); see fn. 4, *ante*.)

B. OEHHA, DART-IC, and Implementing Regulations

Proposition 65 required the Governor to designate a lead agency and other agencies that may be required to implement Proposition 65. (§ 25249.12, subd. (a).) In 1991, the Governor designated OEHHA as the lead agency. (§ 25102, subd. (*o*).) As the lead agency, OEHHA was authorized to promulgate regulations to implement Proposition 65. (§ 25249.12, subd. (a); *Exxon Mobil*, *supra*, 169 Cal.App.3d at p. 1279.) The OEHHA regulations identify the DART-IC as the qualified experts on developmental and reproductive toxicants. DART-IC is a committee of OEHHA. (Regs. § 25102, subds. (c), (t); *California Chamber of Commerce v. Brown* (2011) 196 Cal.App.4th 233 (*Cal. Chamber*).)

C. The Statutory Listing Mechanisms

Section 25249.8 provides four separate listing mechanisms: (1) the Labor Code reference mechanism – "substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code

Section 6382(d)" (§ 25249.8, subd. (a));[9] (2) the qualified experts mechanism – chemicals for which "in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity"; (3) the authoritative body mechanism – "a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity"; and (4) the formally required mechanism – "an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity."[10] (§ 25249.8, subd. (b); see fn. 2, *ante*.)

Regarding the authoritative body mechanism, "[t]he regulations provide that the 'lead agency' (OEHHA) 'shall determine which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.' " (*Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1270, citing Regs. § 25306, subd. (c).) "OEHHA must further determine whether the authoritative body relied upon 'sufficient evidence' of . . . reproductive toxicity as defined in the regulations or did not consider 'scientifically valid' data, but it does not 'substitute its scientific judgment for that of the authoritative body.' " (*Cal. Chamber*, *supra*, 196 Cal.App.4th at pp. 245, 259, citing *Exxon Mobil*, at p. 1283.)

The NTP is identified in Regulation 25306 as an authoritative body for the identification of chemicals as causing reproductive toxicity, but solely as to final reports

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[9] See *Cal. Chamber*, *supra*, 196 Cal.App.4th 233.

[10] The formally required mechanism "involves no independent evaluation by OEHHA or the expert committees. Rather, OEHHA 'shall' list chemicals 'if . . . [it] . . . determines that an agency of the state or federal government has formally required the chemical to be labeled or identified as causing cancer or reproductive toxicity.' " (*Cal. Chamber*, *supra*, 196 Cal.App.4th at p. 245, quoting Regs. § 25902, subd. (a).)

of the NTP-CERHR. (Regs. § 25306, subd. (*l*)(3); see *Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1270 & fn. 6.)[11]

D. The Two-step Process of Proposition 65

As OEHHA and NRDC point out, Proposition 65 prescribes a two-step process. In the first step, the "hazard-identification" stage, the state creates a list of chemicals known to the state to cause cancer or reproductive toxicity. (§ 25249.8, subd. (a); *Exxon Mobil*, *supra*, 169 Cal.App.4th at pp. 1291-1292.) In the second step, which occurs after the chemical is listed, businesses are required to give a " 'clear and reasonable warning' before exposing individuals to the chemical" and are prohibited from knowingly discharging listed chemicals into water or onto land where the chemical will or probably will pass into any source of drinking water. (§§ 25249.5, 25249.6; *Exxon Mobil*, at pp. 1268, 1291-1292.) However, as part of this second step, a business can obtain an exemption from these requirements if it can demonstrate the discharge or release "will not cause any significant amount of the discharged or released chemical to enter any source of drinking water" (§ 25249.9, subd. (b)(1)), or that the exposure to the chemical poses no significant risk at specified exposure levels. (§ 25249.10, subd. (c).)[12] (*Exxon Mobil*, at p. 1268.)

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[11] The other listed authoritative bodies are the United States Environmental Protection Agency, the United States Food and Drug Administration, the International Agency for Research on Cancer (solely as to transplacental carcinogenicity), and the National Institute for Occupational Safety and Health. (Regs. § 25306, subd. (*l*).)

[12] Under section 25249.10, subdivision (c), the business must demonstrate that the chemical "poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical . . . .' " (§ 25249.10, subd. (c); *Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1268; see Regulations §§ 25801, 25803, 25821.) A businesses may also " 'request that the agency set . . . a "safe harbor" level for a specific

Only the first step — hazard identification — is at issue here. As we shall discuss, ACC's arguments pertaining to exposure levels are appropriate for the second step which is not at issue here.

E. Chemicals Known to Cause Cancer or Reproductive Toxicity

" '[O]nly those chemicals that are known, and not merely suspected, of causing cancer or reproductive toxicity must be [placed] on the [Proposition 65] list.' " (*Western Crop, supra*, 80 Cal.App.4th at p. 749, quoting *Deukmejian, supra*, 212 Cal.App.3d at pp. 436-437; see *Styrene, supra*, 210 Cal.App.4th at p. 1101.) However, section 25249.5 does not expressly limit a chemical subject to listing to those known to cause cancer or reproductive toxicity *in humans*. (*Deukmejian*, at p 435.) The chemical agent must be listed even if it is known to be carcinogenic or a reproductive toxin only in animals. (*American Chemistry Council v. Office of Environmental Health Hazard Assessment* (2020) 51 Cal.App.5th 918, 921 (*American Chemistry Council); Western Crop*, at p. 749; *Deukmejian*, at p. 438, fn. 7.)

Regulation 25306 addresses chemicals formally identified by authoritative bodies. Subdivision (d)(1) of Regulation 25306 provides in pertinent part: "a chemical is 'formally identified' . . . when the lead agency determines that: [¶] the chemical . . . is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity."[13] Subdivision (g) provides that

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chemical, if none exists.' " (*Exxon Mobil*, at p. 1291.)

[13] In full, Regulation 25306, subdivision (d), provides: "For purposes of this section a chemical is 'formally identified' by an authoritative body when the lead agency determines that: [¶] (1) *the chemical* has been included on a list of chemicals causing cancer or reproductive toxicity issued by the authoritative body; or *is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity*; or has otherwise been identified as causing cancer or reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action; and [¶] (2) the list, report, or document specifically and accurately identifies the chemical, and has been: [¶] (A) Reviewed by

"as causing reproductive toxicity" means that either "[s]tudies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity," or "[*s*]*tudies in experimental animals* indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, *indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible*." [14] (Italics added.) Thus, as we read Regulation 25306, addressing chemicals that cause reproductive toxicity in animals, it has two components: (1) formal identification of the chemical, within the meaning of subdivision (d)(1), as causing reproductive toxicity in animals, and (2) biological plausibility of adverse reproductive effects in humans pursuant to subdivision (g). As we shall discuss *post*, ACC's contentions implicate the interpretation that OEHHA gives to these component parts of Regulation 25306.

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an advisory committee in a public meeting, if a public meeting is required, or [¶] (B) Made subject to public review and comment prior to its issuance, or [¶] (C) Published by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency, or [¶] (D) Signed, where required, by the chief administrative officer of the authoritative body or a designee, or [¶] (E) Adopted as a final rule by the authoritative body, or [¶] (F) Otherwise set forth in an official document utilized by the authoritative body for regulatory purposes." (Italics added.)

[14] In full, Regulation 25306, subdivision (g), provides: "For purposes of this section, 'as causing reproductive toxicity' means that either of the following criteria have been satisfied: [¶] (1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or [¶] (2) *Studies in experimental animals indicate that there are sufficient data,* taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity*, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible*." (Italics added.)

III. Consideration of the DART-IC Determination and Dr. Tyl's Opinion

We first address ACC's contention that OEHHA abused its discretion by refusing to consider the DART-IC's determination, in which it voted unanimously against listing BPA.[15] This appears to be an issue of first impression as we have found no published cases on point or any that involve a situation where OEHHA and DART-IC disagree on whether a particular chemical should be listed.[16]

ACC points out that DART-IC made its determination based on the same monograph reviewed by OEHHA and notes that DART-IC members expressed skepticism as to whether the conclusions from the animal studies could be extrapolated to humans. ACC emphasizes that all of the OEHHA staff who ultimately would participate in the decision to list BPA attended the DART-IC hearing and further maintains that,

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[15] OEHHA asserts that it *did* consider the opinions of members of the DART-IC, as well as the opinion of Dr. Tyl, ACC's expert. However, OEHHA argues that it was not required to defer or afford great weight to these opinions which, it asserts, differed from the conclusions of the NTP. For its part, ACC asserts that a declaration submitted by OEHHA's general counsel in response to a request to augment the administrative record proves OEHHA did not consider the DART-IC declination. In the declaration, the general counsel stated under oath that " '[t]he DART-IC documents ACC seeks to add to the Administrative Record were not submitted to OEHHA during the listing process for BPA; *they were therefore not considered by OEHHA as part of its determination*' " Read in the context of ACC's request to augment the record, the general counsel's statement pertains to *documents* that were not part of the OEHHA determination. The general counsel did not say OEHHA never considered the determination of the DART-IC or the opinions of its members or of Dr. Tyl, all of which OEHHA was aware without reference to the documents.

[16] In *Western Crop, supra*, 80 Cal.App.4th 741, the plaintiffs asserted that OEHHA usurped DART-IC in deciding to list certain chemicals under the authoritative body listing recommendation based on the formal identification of the United States Environmental Protection Agency. (*Id*. at p. 747.) However, in that case, DART-IC had not made any prior determination regarding the chemicals at issue. This court held that, based on the record before it, there had been no usurpation and the plaintiffs failed to establish that OEHHA abused its discretion in listing the chemical at issue under the authoritative body mechanism. (*Id*. at pp. 749, 757-758.)

despite the fact that OEHHA members were present at the DART-IC meeting, they nonetheless refused to consider the views of the DART-IC panel. If, under an applicable statute or regulation OEHHA were required to consider DART-IC's determination, and if we concluded that OEHHA failed to do so, it is possible those circumstances would establish an abuse of discretion by OEHHA. However, as we shall discuss, we find no such statutory or regulatory requirement, and, accordingly, no such abuse of discretion.

There is no statutory or regulatory provision that requires OEHHA to consider DART-IC's listing declination when determining whether to list a chemical under the authoritative body listing mechanism. On the other hand, Regulation 25306 does set forth mandatory interaction between OEHHA and its committee, DART-IC. Subdivision (i) provides that OEHHA must notice DART-IC with its intention to list a chemical pursuant to the authoritative body mechanism. Thereafter, DART-IC members have 30 days to review and comment on the proposed action. In the matter before us, neither DART-IC nor its members offered any comments pursuant to OEHHA's notice. Subdivision (i) also provides that if OEHHA finds there is no substantial evidence that the criteria in subdivision (g) have been satisfied, OEHHA shall refer the chemical to DART-IC to determine whether, in the opinion of the committee, "the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity." (Regs. § 25306, subd. (i); *Cal. Chamber*, *supra*, 196 Cal.App.4th at p. 245.)[17]

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[17] Regulation 25306, subdivision (i), provides in relevant part: "At least 60 days prior to adding a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall cause to be published in the California Regulatory Notice Register a notice identifying the authoritative body and the chemical, and stating the lead agency's intention to cause the chemical to be added to the list. *Copies of the notice shall be provided to* the Carcinogen Identification Committee or the *DART Identification Committee*, as appropriate, *to permit the* appropriate *Committee*

Subdivision (j) of Regulation 25306, also touches on the relationship between OEHHA and DART-IC in the listing process. It sets forth a provision for reconsideration of OEHHA's listing pursuant to the authoritative body mechanism. OEHHA "shall" reconsider its determination that a chemical has been formally identified as causing reproductive toxicity if it subsequently finds: "(1) there is no substantial evidence that the criteria identified in subsection (e) or subsection (g) have been satisfied, or (2) the chemical is no longer identified as causing cancer or reproductive toxicity by the authoritative body." (Regs. § 25306, subd. (j).) This reconsideration may be initiated by OEHHA or on the request of an interested party, including any member of DART-IC. (Regs. § 25306, subd. (j).) OEHHA "shall refer chemicals under reconsideration . . . to [DART-IC] for a recommendation concerning whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. Pending such reconsideration, the chemical shall remain on the list." (*Ibid.*)[18] No request for reconsideration has been made here.

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at least 30 days to review and comment on the proposed action. Within 30 days following the publication of the notice, *interested parties, including any member of the* appropriate *Committee, shall submit to the lead agency their written objections* to the addition of the chemical to the list of chemicals known to the state to cause cancer or reproductive toxicity, along with any supporting documentation. Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied. *The lead agency shall review such objections. If the lead agency finds that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied, the lead agency shall refer the chemical to the* appropriate *Committee to determine whether, in the Committee's opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity.*" (Italics added.)

[18] Regulation 25306, subdivision (j), provides, in full: "Subsequent to the addition of a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency *shall reconsider its determination* that the chemical has been formally identified as causing cancer or reproductive toxicity if the

Subdivisions (i) and (j) of Regulation 25306, appear to encompass the extent of the interactions mandated by the regulations between OEHHA and DART-IC relative to listing pursuant to the authoritative body mechanism. Thus, these provisions would appear to represent the only obligations OEHHA has relative to DART-IC in the context of the authoritative body listing mechanism. ACC fails to identify any authority for its premise that OEHHA was *required* to take into account the earlier DART-IC determination. Consequently, ACC has failed to establish that OEHHA did not comply with a statutory or regulatory obligation, and, in the absence of evidence to the contrary, we presume regular performance of an official duty. (Cf. *City of Sacramento v. State Water Resources Control Bd.* (1992) 2 Cal.App.4th 960, 976 [the relevant inquiry here is whether the record contains evidence the agency failed to comply with the requirements of its regulatory program; in the absence of contrary evidence, we presume regular performance of official duty]; Evid. Code, § 664 ["It is presumed that official duty has been regularly performed"].)

ACC argues that, because the findings required by Regulation 25306, subdivision (g) relative to the authoritative body mechanism in large measure parallel those made by DART-IC relative to the qualified experts listing mechanism, OEHHA cannot refuse to consider DART-IC's views as to biological plausibility. However, the statutory and regulatory scheme makes clear, and the parties agree, that there are different listing

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lead agency finds: [¶] (1) there is no substantial evidence that the criteria identified in subsection (e) or subsection (g) have been satisfied, or [¶] (2) the chemical is no longer identified as causing cancer or reproductive toxicity by the authoritative body. [¶] *Reconsideration may be initiated by* the lead agency on its own motion, or on a request from an interested party, including *any member of the appropriate Committee*. *The lead agency shall refer chemicals under reconsideration pursuant to this subsection to the appropriate Committee for a recommendation concerning whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. Pending such reconsideration, the chemical shall remain on the list.*" (Italics added.)

mechanisms pursuant to Proposition 65. The state's qualified experts listing mechanism and the authoritative body listing mechanism, both found in section 25249.8, subdivision (b), are separate and distinct means by which a chemical may be listed under Proposition 65.

Moreover, contrary to ACC's contention, the findings required for each listing mechanism are not parallel. The requirement in subdivision (b) of section 25249.8 relative to the qualified expert's mechanism expressly states a standard of proof and specific information the expert panel must consider; the DART-IC may list when "it has *been clearly shown* through scientifically *valid testing according to generally accepted principles* to cause cancer or reproductive toxicity." (Italics added.) That same standard is not expressly tied to the authoritative body mechanism, which requires OEHHA to list the chemical "if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity." (§ 25249.8, subdivision (b); see fn. 2, *ante*.) Thus, as OEHHA points out, DART-IC and OEHHA answer different questions under the two separate listing mechanisms. DART-IC acts as an independent finder-of-fact under the qualified experts listing mechanism. OEHHA, on the other hand, determines whether there was sufficient evidence in the record to support the authoritative body's formal identification of the chemical as a reproductive toxicant. In listing pursuant to the authoritative body mechanism, OEHHA cannot substitute its judgment, or that of DART-IC, for that of the authoritative body. And OEHHA's determination under section 25249.8, subdivision (b), and Regulation 25306 are to be based on its own interpretation as to the authoritative body's conclusions, not DART-IC's. Nothing in section 25249.8, subdivision (b) or the regulations, suggests OEHHA must consult with or consider DART-IC's previously announced opinion except when made in a formal comment after OEHHA's notice of intent to list. Where DART-IC makes formal comment in response to OEHHA's notice of intent, Regulation 25306, subdivision (i) requires OEHHA to consider such comment, but as noted, no post-notice-

of-intent comment was made by DART-IC here. Nor did any DART-IC member make a request for reconsideration under Regulation 25306, subdivision (j). While it may be reasonable and logical for OEHHA to take into account DART-IC's previous conclusions on the matter, there is no statutory or regulatory requirement that it do so.

We cannot conclude that OEHHA abused its discretion in purportedly declining to do something it had no obligation or direction to do. Therefore, even if OEHHA did not consider the DART-IC determination, it cannot be said to have abused its discretion in failing to do so or even in failing to consider the reasons for the DART-IC listing declination.

Nor are we persuaded that OEHHA abused its discretion in not adopting Dr. Tyl's opinion. OEHHA concluded that NTP in the monograph formally identified BPA as a reproductive toxicant, and that an association between adverse reproductive effects in humans and BPA is biologically plausible. As such, it determined it was required to list BPA under the authoritative body listing mechanism, notwithstanding Dr. Tyl's disagreement.

And as we next discuss, OEHHA's decision was not arbitrary, capricious, or entirely lacking in evidentiary support.

IV. OEHHA's Authoritative Body Listing Determination

A. ACC's Contentions

ACC contends that OEHHA abused its discretion in concluding that NTP formally identified BPA as a reproductive toxicant in the monograph. According to ACC, OEHHA's conclusion was not supported by the content of the monograph; was based on language different than that which NTP employs when it formally identifies a chemical as a reproductive toxicant; conflicted with OEHHA's own regulations defining formal identification of a reproductive toxicant; and resulted from the misapplication of controlling case law.

We disagree. We conclude that OEHHA did not abuse its discretion in interpreting its own regulations and determining NTP identified BPA as a reproductive toxicant.

B. Interpretation of Regulation 25306 Subdivisions (d)(1) & (g)

Pursuant to Regulation 25306, subdivisions (d)(1) and (g), OEHHA concluded that NTP identified BPA as a reproductive toxicant. Thus, how those provisions are to be interpreted is at issue here.

As the *Exxon Mobil* court stated, our analysis of the meaning of OEHHA's regulations "necessarily is guided by the applicable standard of review. 'As a starting point, the interpretation of an administrative regulation is subject to the same principles as the interpretation of a statute. [Citation.] However, there is an important difference between the interpretation of a statute and the interpretation of a regulation. " 'The Legislature has no authority to interpret a statute.' " [Citations.] On the other hand, where the language of the regulation is ambiguous, it is appropriate to consider the agency's interpretation. [Citation.] Indeed, we defer to an agency's interpretation of a regulation involving its area of expertise, " 'unless the interpretation flies in the face of the clear language and purpose of the interpretive provision.' " ' " (*Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1280.) Consequently, "our inquiry is not the 'correct' interpretation of [the regulation], but whether the interpretation offered by OEHHA is reasonable in light of the regulation's language and purpose." (*Ibid*.)

C. Component Elements of Regulation 25306 Relative to Reproductive Toxicity in Animals

As noted, Regulation 25306, addressing chemicals that cause reproductive toxicity in animals, has two component elements: (1) formal identification of the chemical, within the meaning of subdivision (d)(1), as a reproductive toxicant in animals, and (2) biological plausibility of adverse reproductive effects in humans.

1. Formal Identification as a Reproductive Toxicant

Regulation 25306, subdivision (d)(1), provides that a chemical is "formally identified" by an authoritative body when, among other possibilities, OEHHA determines that the chemical "is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity" and certain other requirements regarding the report are met. (See fn. 13, *ante*.) Here, the monograph stated: "Although there is no direct evidence that exposure of people to [BPA] adversely affects reproduction or development, *studies with laboratory rodents show that exposure to high dose levels of [BPA] during pregnancy and/or lactation can reduce survival, birth weight, and growth of offspring early in life, and delay the onset of puberty in males and females*." (Italics added.) The monograph characterized these " 'high' dose effects" as not scientifically controversial, and stated that they "provide *clear evidence of adverse effects on development in laboratory animals*." (Italics added.) The monograph further stated that the "NTP finds that there is *clear evidence of adverse developmental effects at 'high' doses of [BPA] in the form of fetal death, decreased litter size, or decreased number of live pups per litter in rats . . . and mice . . . , reduced growth in rats . . . and mice . . . , and delayed puberty in male mice . . . male rats . . . and female rats . . . .*" (Italics added.) And the monograph characterized the weight of the evidence that BPA causes adverse developmental or reproductive effects in laboratory animals based on high dose developmental toxicity as indicating "[c]lear evidence of adverse effects," the strongest showing along the weight-of-the-evidence continuum it employs. (See fn. 5, *ante*.) It was this conclusion in the monograph that OEHHA relied upon in deciding to list BPA.

OEHHA did not abuse its discretion in concluding that NTP, based on the high-dose animal testing, formally identified BPA as a chemical that causes reproductive toxicity. The italicized language in the monograph passages set forth *ante* establishes as

much, and the monograph emphasized that these " 'high' dose effects" were not scientifically controversial.

And the statutes and the case law are clear that, for a chemical to be formally identified as causing cancer or reproductive toxicity, it need not be proven that the chemical causes cancer or reproductive toxicity *in humans.* Proposition 65 applies to those chemicals which authoritative bodies have already determined cause cancer or reproductive toxicity in humans *or experimental animals*. (*American Chemistry Council, supra*, 51 Cal.App.5th at p. 921; *Deukmejian, supra*, 212 Cal.App.3d at p. 441.) A finding that a chemical is known to cause reproductive toxicity "can be 'satisfied' by '[s]tudies in experimental animals [which] indicate . . . an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.' "[19] (*Western Crop, supra*, 80 Cal.App.4th at p. 749, quoting former Regs., tit. 22, § 12306, renumbered as Cal. Code Regs., tit. 27, § 25306.) In the passages of the monograph set forth *ante*, NTP formally identified BPA as a chemical known, not merely suspected, to cause reproductive toxicity, albeit based on high-dose animal studies.

As ACC points out, the monograph acknowledged the existence of a scientific controversy over interpretation of " 'low' dose findings." However, it was the high-dose studies, and the NTP's conclusion with regard thereto, not the low-dose studies or the studies of effects in humans, that formed the basis for OEHHA's conclusion that NTP had formally identified BPA as a chemical known to the state to cause reproductive toxicity.

Regarding whether current human exposures to BPA are high enough to be cause for concern, the monograph concluded: "[p]ossibly." The monograph observed that the " 'high' dose effects of [BPA] in laboratory animals that provide clear evidence for

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[19] We discuss biological plausibility in part IV.C.2 of the Discussion, *post*.

adverse effects on development, i.e., reduced survival, birth weight, and growth of offspring early in life, and delayed puberty in female rats and male rats and mice, are observed at levels of exposure that far exceed those encountered by humans." The monograph continued: "However, estimated exposures in pregnant women and fetuses, infants, and children are similar to levels of [BPA] associated with several 'low' dose laboratory animal findings of effects on the brain and behavior, prostate and mammary gland development, and early onset of puberty in females. When considered together, these laboratory animal findings provide limited evidence that [BPA] has adverse effects on development." The monograph then stated: "The conclusion of similarities between exposures of certain human populations and laboratory animals treated with 'low' doses of [BPA] is supported by multiple approaches. For this reason, *the possibility that human development may be altered by [BPA] at current exposure levels cannot be dismissed*." (Italics added.) While this language clearly speaks of BPA as being a reproductive toxicant, we agree with OEHHA that the discussion of whether current levels of human exposure are high enough to warrant concern is a question to be addressed to the second step of Proposition 65's two-step process involving an exemption related to the level of exposure, not to the first step concerning hazard identification. (See *Exxon Mobil*, *supra*, 169 Cal.App.4th at pp. 1291-1292 [noting that Exxon could present its exposure argument to OEHHA in the second step of Proposition 65, seeking a Safe Use Determination, or it could present its argument to the court in the future if it is ever sued for failing to provide a Proposition 65 warning; but Exxon's exposure argument is not relevant to determining whether a chemical should be listed].)

We are not persuaded by ACC's arguments that the NTP did not formally identify BPA in the monograph here because it did not employ the same language that it had previously used in other monographs in which it formally identified other chemicals. For example the monograph discussed in *Exxon Mobil* stated: " 'In this case, recognizing the lack of human data and the evidence of effects in laboratory animals, the *NTP judges* the

scientific evidence sufficient to conclude that DIDP is a developmental toxicant and could adversely affect human development if the levels of exposure were sufficiently high.' " (*Exxon Mobil, supra*, 169 Cal.App.4th at p. 1285, italics added.) ACC points out that similar language is used in eight other monographs, arguing that when NTP identifies a chemical as a developmental or reproductive toxicant, it does so stating, "what it *judges* as its conclusion."

This argument must be rejected. No specific language is required. And as we have concluded *ante*, the language of the monograph supports OEHHA's determination that NTP formally identified BPA as a reproductive toxicant in animals; thus, OEHHA did not abuse its discretion in determining that NTP formally identified BPA as a chemical known to cause reproductive toxicity merely because NTP did not use language it had previously used. We agree with OEHHA that the language employed in other monographs is not relevant to our determination here. In any event, as OEHHA notes, the language it identifies as the phase one hazard identification – " '[c]lear evidence of adverse effects' " – used in the monograph at issue here is identical to the same language used in each of the other monographs ACC offered for comparison.

At oral argument, ACC relied on *Styrene, supra*, 210 Cal.App.4th 1082, in a way not advanced in its briefing on appeal. ACC pointed out that the court in *Styrene* held the chemical at issue there could not be listed because the authoritative body only found the chemical was "possibly" carcinogenic. ACC argued the *Styrene* court emphasized the Proposition 65 requirement that the chemical be known, and not merely suspected, to cause cancer or reproductive toxicity in order to list, and argued that *Styrene* is analogous because the authoritative body here found there was insufficient evidence to conclude BPA is a reproductive toxicant in humans, although it could not dismiss the possibility. ACC argued that Proposition 65 requires known risks to humans, and since the NTP report did not make that finding, reversal is warranted here. ACC's newly placed reliance on *Styrene* is misplaced for two reasons.

First, the chemical at issue in *Styrene* was found by the authoritative body to "possibly" be carcinogenic to humans based on "limited evidence of carcinogenicity in *both humans and experimental animals*." (*Styrene*, *supra*, 210 Cal.App.4th at p. 1092, italics added.) From this, the court held that the findings in the authoritative body's monograph did not satisfy the standard of section 25249.8 that the chemical agent be "known to cause cancer." (*Styrene*, at p. 1101.) But here, unlike in *Styrene*, NTP found at high dose levels "clear evidence of adverse effects on development in laboratory animals." In other words, where the evidence as to both humans and experimental animals was lacking in *Styrene*, here there was evidence of the adverse effects on animals. Indeed, the court in *Styrene* distinguished the chemical at issue there with the chemical at issue in *Deukmejian*, *supra*, 212 Cal.App.3d 425, for a similar reason. (*Styrene*, at p. 1095.) As the *Styrene* court noted, in *Deukmejian* the authoritative body found there was sufficient evidence of carcinogenicity in animals, whereas the issue before the court in *Styrene* was "whether substances identified by reference in [the authoritative body's] monograph for which there is not sufficient evidence of carcinogenicity *in either humans or animals* must be included on the list." (*Ibid*.) *Styrene* does not address the possibility a chemical is a reproductive toxicant in humans when there is clear evidence it is a reproductive toxicant in experimental animals.

Second, ACC conflates the task of determining whether a chemical causes cancer with determining whether the chemical causes reproductive toxicity. *Styrene* involved carcinogenicity not reproductive toxicity. Although the *Styrene* court had no occasion to interpret or otherwise consider the relevant regulations, we note the regulations governing carcinogens and reproductive toxicants in animals are different. Regulation 25306, subdivision (e)(2) governs carcinogens and provides: "For purposes of this section, 'as causing cancer' means that . . . the following criteria has been satisfied: [¶] (2) Sufficient evidence of carcinogenicity exists from studies in experimental animals. For purposes of this paragraph, *"sufficient evidence" means studies in experimental animals*

indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset." (Italics added.) As the italicized text highlights, the provision addressing carcinogenicity in experimental animals has very different criteria compared to the provision related to reproductive toxicants in experimental animals, Regulation 25306, subdivision (g)(2). (See fn. 14, *ante*.) Indeed, there is no biological plausibility component to the regulatory provision governing carcinogens. *Styrene* is of no help to ACC.

We conclude OEHHA did not abuse its discretion when it concluded NTP has formally identified BPA as a reproductive toxicant in animals under Regulation 25306, subdivision (d)(1). We further discuss case law relevant to OEHHA's determination of formal identification, and additionally focus on the "biological plausibility" requirement for listing under subdivision (g) of Regulation 25306.

2. Biological Plausibility

ACC asserts that OEHHA abused its discretion in concluding that the adverse effects found in high-dose rodent studies were biologically plausible in humans. According to ACC, the monograph does not support the conclusion that NTP found the results in rodent studies biologically plausible in humans and OEHHA may not merely *assume* such biological plausibility. Additionally, ACC asserts that OEHHA's review of the studies themselves is insufficient to establish that NTP found biological plausibility.

These arguments are similar to those made in *Exxon Mobil*. Exxon asserted that "[T]he NTP Brief [on the chemical at issue] did not consider the mandatory criteria under Regulations, section 25306, subdivision (g) . . . , and did not make the required determination that an association between adverse reproductive effects in humans and [the chemical] is biologically plausible." (*Exxon Mobil*, *supra*, 169 Cal.App.4th at

p. 1275.) Exxon argued that "OEHHA may list a chemical based on the 'authoritative body' provision of section 25249.8 *only* if an authoritative body's report includes the findings prescribed by regulation 25306(g)—i.e., that there are sufficient data from valid animal studies to demonstrate that adverse effects in humans are biologically plausible." (*Exxon Mobil*, at p. 1277.) Exxon maintained that an authoritative body's report considering animal studies that neither takes into account the scientific criteria set forth in Regulation 25306, subdivision (g)(2), " 'nor contains the required finding of "biological plausibility" in humans does not (and cannot) satisfy the requirements of [regulation 25306(g)(2)].' " (*Exxon Mobil*, at p. 1278.) OEHHA responded that the authoritative body listing mechanism is triggered if the authoritative body formally identifies a chemical in a report and satisfies the report formalities set forth in Regulation 25306, subdivision (d)(2) (see fn. 13, *ante*), but the authoritative body's report "need not include the detailed findings set out in [R]egulation 25306, [subdivision] (g). Instead, once the chemical is 'formally identified' by an authoritative body as a developmental toxicant, OEHHA reviews the scientific record before the authoritative body to determine whether there is substantial evidence to support a listing. If it concludes on the basis of its review that the [R]egulation 25306(g) criteria are satisfied—i.e., that the experimental animal data considered by the authoritative body are sufficient to support a conclusion that an association between adverse reproductive effects in humans and the toxic agent is biologically plausible—then it lists the chemical." (*Exxon Mobil*, at pp. 1278-1279.) OEHHA reprises this argument here.

The *Exxon Mobil* court held: "To list a chemical pursuant to [R]egulations, 25306 . . . , OEHHA must conclude that an authoritative body has determined that … the experimental animal data are sufficient to support a conclusion that adverse effects in humans are biologically plausible. Nothing in [R]egulations, section 25306 suggests, however, that OEHHA must base this conclusion *solely* on the authoritative body's report. Rather, as OEHHA suggests, the language of Regulations, section 25306 is broad

enough to allow OEHHA to premise its conclusion on the authoritative body's report *and other factors,* such as the scientific literature on which the authoritative body relied and OEHHA's knowledge of the authoritative body's methodology. In other words, so long as OEHHA is able to conclude on the basis of the authoritative body's report *and the underlying scientific record* that an authoritative body has identified a chemical as a reproductive toxicant and that the identification takes the regulatory criteria into account, OEHHA may list it pursuant to Regulations, section 25306." (*Exxon Mobil, supra,* 169 Cal.App.4th at pp. 1280-1281.) Later in the opinion, the *Exxon Mobil* court reiterated its conclusion that "OEHHA properly can conclude that the authoritative body made the necessary findings based on OEHHA's review of the scientific literature on which the authoritative body relied and its knowledge of the authoritative body's methodology." In other words, OEHHA can look to the *entire record* before it in determining whether the authoritative body made the [R]egulation 25306(g) findings. (*Exxon Mobil,* at p. 1282.)

The *Exxon Mobil* court concluded that its interpretation Regulation 25306, subdivision (g), was supported by, among other things, the final statement of reasons (FSOR), which was issued in connection with the adoption of that regulation as required by Government Code section 11346.9. (*Exxon Mobil, supra,* 169 Cal.App.4th at p. 1282.) After discussing statements set forth in the FSOR, the *Exxon Mobil* court explained the regulatory provision concerning the designation of authoritative bodies: "Considered together, we understand these statements to mean that when designating a body as authoritative within the meaning of the statute, the DART Committee determines whether the body uses 'the same or substantially the same criteria' set out in Regulation 25306(g). Only if it does will it be deemed an 'authoritative body.' The authoritative body designation thus allows OEHHA to *presume* that the body made the prescribed findings when it determined a chemical to be a reproductive toxicant: 'In effect, there is a presumption that the authoritative body properly applied the criteria.' " (*Exxon Mobil,* at p. 1283, quoting FSOR, *supra,* at p. 25.)

Like ACC argues here, Exxon argued "that OEHHA abused its discretion by basing its listing decision solely on data derived from experimental animal studies." (*Exxon Mobil, supra,* 169 Cal.App.4th at p. 1288.) The *Exxon Mobil* court disagreed. (*Ibid*.) The court reiterated that Regulation 25306, subdivision (g)(2), "expressly permits a finding of reproductive toxicity to be based on experimental animal studies, so long as the studies indicate that 'there are sufficient data . . . indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.' [Citation.] Nothing in the regulation thus precludes OEHHA from concluding that there is substantial evidence of biological plausibility based solely on animal studies—to the contrary, the regulation appears to contemplate extrapolation from animal studies to humans. " (*Exxon Mobil,* at p. 1288.)

The court in *Exxon Mobil* then went on to discuss the presumption of biological plausibility relied on by OEHHA here: "Further, there is support in the record for OEHHA's assertion that it is a 'generally accepted toxicological assumption that, absent evidence to the contrary, a chemical that causes developmental harm in experimental animals, will cause similar harm in humans.' In this regard, the Guidelines for Developmental Toxicity Risk Assessment promulgated by the federal Environmental Protection Agency[**20**] state: '[I]t is assumed that an agent that produces an adverse developmental effect in experimental animal studies will potentially pose a hazard to humans following sufficient exposure during development. This assumption is based on the comparisons of data for agents known to cause human developmental toxicity [citations], which indicate that, in almost all cases, experimental animal data are

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20 The Guidelines for Developmental Toxicity Risk Assessment are part of the administrative record here, and OEHHA cited the Guidelines in discussing the presumption of biological plausibility in response to a comment during the administrative process. (See fn.7, *ante*.)

predictive of a developmental effect in humans.' [Citation.] NTP apparently operates under a similar assumption: 'In the absence of human data to the contrary, it is assumed that the effects observed in laboratory animals are relevant to humans.' " (*Exxon Mobil, supra*, 169 Cal.App.4th at pp. 1288-1289, fn. omitted, citing *Deukmejian, supra*, 212 Cal.App.3d at p. 438, fn. 7.) Because OEHHA interprets its own regulation's requirement of biological plausibility to incorporate this presumption and because the court in *Exxon Mobil* acknowledged as much, we defer to OEHHA's continuing interpretation. OEHHA's interpretation does not "fl[y] in the face of the clear language and purpose of" section 25249.8 or Regulation 25306, and "[it] is reasonable in light of the regulation's language and purpose." (*Exxon Mobil*, at p. 1280.)

We further agree with OEHHA that it was not necessary for the monograph to contain express language specifically stating that "[s]tudies in experimental animals indicate that there are sufficient data . . . indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (Regs. § 25306, subd. (g)(2).) As the *Exxon Mobil* court noted, the language of Regulation 25306 is broad enough to allow OEHHA to premise its conclusion on the authoritative body's report *and other factors*, such as the scientific literature on which the authoritative body relied and OEHHA's knowledge of the authoritative body's methodology. (*Exxon Mobil, supra*, 169 Cal.App.4th at p.1281.) "So long as OEHHA is able to conclude on the basis of the authoritative body's report *and the underlying scientific record* that an authoritative body has identified a chemical as a reproductive toxicant and that the identification takes the regulatory criteria into account, OEHHA may list it pursuant to Regulations, section 25306." (*Ibid*.; see also *Western Crop*, *supra*, 80 Cal.App.4th at p. 754 ["The clear implication" of Regulation 25306, subdivision (g) is that OEHHA has the authority "to examine the record" relative to the authoritative body's report on the chemical "to determine whether there is substantial evidence that the subdivision (g) criteria have been met"].) We do not find any provision in the regulations

that requires the authoritative body's report to specifically state that "[s]tudies in experimental animals indicate that there are sufficient data . . . indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (Regs. § 25306, subd. (g)(2).) Consideration of the "*entire record*" (*Exxon Mobil*, at p. 1282) before OEHHA includes consideration of whether there are in that record "[s]tudies in experimental animals [that] indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (Regs. § 25306, subd. (g); *Exxon Mobil*, at p. 1282.) Therefore, we turn to the record to consider whether OEHHA's determination that NTP considered criteria in subdivision (g) and whether biological plausibility can be determined from the monograph and the studies upon which it relied.

OEHHA referenced the studies in the monograph in its notice of intent to list BPA. It stated the "studies were reviewed by OEHHA with regard to the criteria in the regulation (Section 25306(g)(2)). Information reviewed in these studies included experimental design, route administration, numbers of test animals, choice of species, choice of dosage levels and maternal toxicity."

Our own review of the monograph reveals that it discussed animal studies involving rats, mice, and monkeys. In describing how it reached its conclusions in the monograph, NTP stated: "Scientific decisions concerning health risks are generally based on what is known as the 'weight-of-evidence.' " "[I]n an effort to glean information that might contribute to understanding the numerous reported effects of [BPA], NTP evaluated many individual study reports. Attention was paid to issues of sample size, control for litter effects, and various other aspects of experimental design;

however, experimental findings were initially evaluated in relation to their biological plausibility and consistency across studies by multiple investigators. Studies were then evaluated as to their adequacy of experimental design and the likelihood that any inconsistent outcomes resulted from differences or shortcomings in experimental design." The monograph discussed route administration across different studies, specifically oral administration versus subcutaneous administration, and how studies involving non-oral administration should be interpreted. The monograph also discussed variations in doses administered in different studies, and distinguished between low-dose and high-dose studies. NTP dedicated a section of the monograph to discussion of the "impact of limitations in experimental design" and how studies with such limitations should be interpreted. (Capitalization omitted.) NTP observed that a number of the low-dose studies had been characterized as having been "experimentally well-conducted," and as having "high utility." The record amply supports OEHHA's finding that the NTP took into account parameters required by Regulation 25306, subdivision (g).

Additionally, as noted, consistent with *Exxon Mobil*, OEHHA applies the generally accepted presumption of biological plausibility, where, " 'absent evidence to the contrary, a chemical that causes developmental harm in experimental animals, will cause similar harm in humans.' " (*Exxon Mobil, supra,* 169 Cal.App.4th at p. 1288.)[21] Evidence to the contrary might include evidence that the animal has a particular physical structure that is harmed but the same physical structure is not present in humans or evidence the animal in question metabolizes the chemical differently than humans. No

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[21] Courts have recognized that human testing is unethical. (*American Chemistry Council*, *supra*, 51 Cal.App.5th at p. 921; *Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1289, citing *Deukmejian, supra,* 212 Cal.App.3d at p. 438, fn. 7.) Accordingly, the principle of extrapolating from evidence effects in animals to humans " 'has been accepted by all health and regulatory agencies, and is regarded widely by scientists in industry and academia as a justifiable and necessary inference.' " (*Deukmejian*, at p. 438, fn. 7.)

evidence "to the contrary" sufficient to rebut the presumption has been identified by ACC.[22]

Additionally, statements in the monograph which touch on the subject do not refute biological plausibility, and, if anything, support it. The monograph stated that BPA can "*possibly*" affect human development or reproduction. OEHHA stated in a response to comments during the administrative process: "That conclusion is equivalent to concluding that such effects are biologically plausible in humans." We agree. If there was evidence to the contrary sufficient to rebut the presumption of biological plausibility, this "possibility" would not exist. The monograph also stated, "Although there is *no direct evidence* that exposure of people to [BPA] adversely affects reproduction or development, studies with laboratory rodents show that exposure to high dose levels of [BPA] during pregnancy and/or lactation can reduce survival, birth weight, and growth of offspring early in life, and delay the onset of puberty in males and females." (Italics added.) Noting the absence of "direct evidence," and then immediately segueing into the animal evidence findings suggests that that animal testing results are indirect or circumstantial evidence of reproductive toxicity in humans. It can be reasonably inferred from this that there is insufficient evidence to rebut the presumption and, again, ACC has identified no such evidence. The monograph continued: "Recognizing the lack of data on the effects of [BPA] in humans and despite the limitations in the evidence for 'low' dose effects in laboratory animals . . . , *the possibility that* [*BPA*] *may alter human development cannot be dismissed*." (Italics added.) OEHHA stated in response to comment the aforementioned statement "represents NTP's conclusion that developmental

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[22] Regarding metabolism, OEHHA stated, in response to comments during the administrative process, that it "reviewed the discussion of metabolism in the NTP-CERHR document and did not find any information that conflicted with NTP's conclusion that BPA 'possibly' could affect human reproduction or development." Nor have we.

toxicity of BPA is biologically plausible in humans." Again, we agree because if there were evidence sufficient to rebut the presumption of biological plausibility, there would be no such possibility.

At oral argument, ACC focused on Figure 2a in the monograph, which is labeled, "The weight of evidence that [BPA] causes adverse developmental or reproductive effects in humans" and states, regarding developmental and reproductive toxicity: "Insufficient evidence for conclusion." But this conclusion as summarized in Figure 2a does not explain that conclusion and does not exclude biological plausibility. The text of the monograph explains: "In the case of [BPA], *evidence from a limited number of studies in humans* exposed to [BPA] is not sufficient to reach conclusions regarding possible developmental or reproductive hazard. In contrast, there is a large literature of laboratory animal studies." (Italics added.) It further stated: there "is also *insufficient evidence from studies in humans* to determine if [BPA] *does or does not cause* developmental toxicity when exposure occurs prenatally or during infancy and childhood." (Italics added.) As the italicized text reveals, it appears the conclusion summary in Figure 2a that there was "[i]nsufficient evidence for conclusion" was based on the limited number of human studies. Thus, that conclusion does not mean NTP found that biological plausibility could not be determined from experimental animal studies.

Our conclusion in this regard is buttressed by other text in the monograph. For example, the monograph stated: "The NTP concurs with the CERHR Expert Panel on [BPA] that the results of neurological and behavioral studies of exposures of laboratory animals to [BPA] during development *raise questions about possible risks to human development*." (Italics added.) The monograph continued: "The conclusion of similarities between exposures of certain human populations and laboratory animals treated with 'low' doses of [BPA] is supported by multiple approaches. For this reason, *the possibility that human development may be altered by [BPA] at current exposure*

levels cannot be dismissed." (Italics added.) Again, if there was evidence to the contrary sufficient to rebut the presumption of biological plausibility, there would be no possible "risks to human development" and the possibility that human development may be altered by BPA at current exposure levels *could be dismissed*.

Additionally, NTP in the monograph's conclusions expressed "*some concern* for exposures in fetuses, infants, and children based on a number of laboratory animal studies reporting that 'low' level exposure to [BPA] during development can cause changes in the brain and behavior. [T]he NTP has *some concern* for exposures to these populations based on effects on the prostate gland observed in laboratory animals." The monograph acknowledged the need for further study, and then stated: "because these effects in animals occur at [BPA] exposure levels similar to those experienced by humans, *the possibility that [BPA] may alter human development cannot be dismissed*." (Italics added.) Again, no such possibility would exist if there was evidence sufficient to rebut the presumption of biological plausibility.

While these statements cannot be characterized as categorically stating there is an established association between adverse reproductive effects in humans and BPA, they do not undermine the conclusion, and in fact support the conclusion, that such an association is *biologically plausible* by suggesting the absence of sufficient contrary evidence to rebut the presumption of biological plausibility.

In addressing the presumption of biological plausibility, ACC seeks to distinguish the instant case from *Exxon Mobil*, where the court recognized the presumption in connection with reproductive toxicity. It asserts that, in *Exxon Mobil,* OEHHA did not resort to "speculation," like ACC asserts OEHHA does here. This is because in *Exxon Mobil*, the NTP "expressly stated that ' "the NTP judges the scientific evidence sufficient to conclude that DIDP is a developmental toxicant and could adversely affect human development . . . ." ' " However, in the monograph here, the NTP did conclude that BPA could *possibly* affect human development and reproduction, and further stated,

"[r]ecognizing the lack of data on the effects of [BPA] in humans and despite the limitations in the evidence for 'low' dose effects in laboratory animals . . . , the *possibility* that [BPA] may alter human development cannot be dismissed." (Italics added.) While less direct than the statements in the *Exxon Mobil* monograph, these statements, along with the presumption of biological plausibility, provide support for a finding that "an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (Regs. § 25306, subd. (g)(2).)

ACC argues that the dosages administered to laboratory animals is far in excess of the highest estimated daily intake BPA in children, adults or workers, essentially arguing that biological plausibility has not been established because humans are not exposed to such dosages. ACC focuses on the fact that "choice of dosage" is listed as a factor for consideration in Regulation 25306, subdivision (g)(2). (See fn. 14, *ante*.) But OEHHA did "take into account" the parameters listed in that provision, including "choice of dosage," so there was no abuse of discretion. As for the issue of whether humans are exposed to BPA at levels high enough to pose a risk, as we have said, that is a matter to be addressed in the second step of Proposition 65, which allows businesses the opportunity to prove no significant risk at certain levels of exposure. (§25249.10, subd. (c); see fn. 12, *ante*; *Exxon Mobil*, *supra*, 169 Cal.App.4th at pp. 1291-1292.)

Lastly, ACC cites various reports by various governmental bodies around the world indicating BPA is safe for humans for various uses.[23] Again, this information is

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[23] These agencies include the United States Food and Drug Administration (FDA), the European Food Safety Authority, Health Canada, Japan's National Institute of Advanced Industrial Science and the World Health Organization. According to ACC, the FDA stated in 2008 "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults." ACC asserts that in 2013, the FDA stated: " 'Based on FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.' " In 2014, according to ACC, the FDA concluded that

pertinent to Proposition 65's second step allowing businesses to prove BPA presents an insignificant risk. It does not establish that OEHHA abused its discretion in listing BPA in Proposition 65's first step related to hazard identification.

In light of the presumption of biological plausibility applied to reproductive toxicants (*Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1288), the foregoing statements in the monograph from which biological plausibility can be inferred based on the presumption, and OEHHA's determination as to NTP's consideration of the parameters required by subdivision (g) of Regulation 25306, we conclude that OEHHA's determination as to biological plausibility was reasonable and not "arbitrary, capricious, or entirely lacking in evidentiary support." (*Id*. at p. 1277.) We thus conclude OEHHA did not abuse its discretion in concluding there was sufficient data in the monograph and

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"FDA's current perspective, based on its most recent safety assessment, is that BPA is safe at the current levels occurring in foods." ACC also asserts that in 2015, the FDA's Acting Chief Scientist advised OEHHA that the FDA, based on a four-year assessment of over 300 scientific studies, "reaffirm FDA's determination that BPA is safe provided that it is used in accordance with our regulations." But we note that not only was the 2015 declaration not part of the administrative record here, but also that it was apparently rejected by DART-IC because that body concluded BPA is a female reproductive toxicant in the administrative process for which that declaration was submitted. (See fn. 4, *ante*.) Also, NRDC points out that many government agencies have actually banned BPA for various usages. According to NRDC, Canada and the European Union have banned the use of BPA in infant feeding bottles. Connecticut and Vermont banded BPA in all reusable food and beverage containers. California, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, Nevada, New York, Washington, and Wisconsin have banned the use of BPA in certain products intended for children. ACC acknowledges these bans, but asserts "each and every one of these bans has been the result of political lobbying by the NRDC and/or like-minded groups, not impartial science. As such, these politically motivated bans do not support any listing here." We need not consider these arguments, which might be pertinent to the second step in Proposition 65, because here we address only the first step, hazard identification, based on the monograph, not the second step, which includes an opportunity for businesses to show the risk to humans is insignificant.

the studies upon which the monograph was based indicating that an association between adverse reproductive effects in humans and BPA was biologically plausible.

D. Conclusion

We conclude that OEHHA did not abuse its discretion in listing BPA based on the monograph. Therefore, we conclude that the trial court did not abuse its discretion in denying ACC the relief requested in the amended complaint.

DISPOSITION

Our previously issued stay is vacated and the judgment is affirmed. Respondents shall recover their costs on appeal. (Cal. Rules of Court, rule 8.278(a)(1), (2).)

/s/
MURRAY, J.

We concur:

/s/
BLEASE, Acting P. J.

/s/
DUARTE, J.